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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,534	09/01/1999	THOMAS M. KUNDIG	C9015-2007	2743

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/380,534

Applicant(s)

KUNDIG, THOMAS M.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2002 and 04 June 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 39-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Basis of Examination***

This Office Action is based on the copy of the Supplemental Response and Amendment faxed to examiner on 6/4/02 which will be entered as of this date. The Supplemental Response and Amendment mailed on May 31, 2002 has not yet been matched with the case.

### ***Election/Restrictions***

Applicant elected without traverse claims 1-21 and 39-65 in Paper No. 12. Therefore claims 38 and 71 as presented in Supplemental Response will not be considered as they are withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 39-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in reciting "administration of the antigen distal to the lymphatic system." It is not clear how something can be distal to the lymphatic system.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 8, 9, 10, 14, 39, 43-52, 55-59, 61-70 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINS et al. (U. S. Patent No. 4,455,142). Martins discloses a method of inducing and sustaining a CTL response by continuously delivering a single or multiple antigen(s) to a mammal (col. 3, lines 57-68; col. 4, lines 10-40). These antigens will progress to the lymphatic system during delivery.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 5, 6, 11, 12, 13, 15, 16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 1 and 4 above, and further in view of KUNDIG (Science. 268:1343-1347). Martins discloses the claimed innovation except for delivering the antigen directly to the lymphatic system, treating cancer, using a cytokine, or an osmotic pump. Kundig discloses that delivering an antigen with a cytokine is well-known in the art, but that delivery can also be made directly to the cytokine-rich lymphatic system. It would

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have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kundig in the invention of Martins in order to provide a tumor vaccination strategy to make tumors immunogenic. It is notoriously well-known in the art to use osmotic pumps to deliver a desired therapeutic composition.

Claims 17, 18, 19, 41, 42, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 4, 39, and 48 above, and further in view of FALO, Jr, et al. (U. S. Patent No. 5,951,975). Martins discloses the claimed invention except for delivery of a MAGE-1 antigen. Fallo teaches utilizing a MAGE-1 antigen to induce a CTL response in a patient (col. 4, lines 20-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Fallo in the invention of Martins in order to stimulate CTL production and destruction of tumor cells without having to identify antigens for each specific tumor (col. 3, lines 38-45).

Claims 40 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 39 and 59 above, and further in view of EBERLEIN et al. (U. S. Patent No. 5,550,214). Martins discloses the claimed invention except that that the polypeptide antigen is 8-10 amino acids. Eberlein teaches the use of polypeptide antigens of 9 and 10 amino acids (col. 2, lines 29-61; col. 3, lines 20-28; col. 17, line 56 - col. 18, line 60). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eberlein in the invention of Martins in order to initiate immune responses against tumor cells only (col. 2, lines 18-23).

***Response to Arguments***

Applicant argues that Martins does not expressly teach every element of the claimed invention, specifically that he does not disclose inducing an immunologic CTL response, but rather for potentiating a response. The examiner takes the position that Martins teaches inducing, maintaining, as well as potentiating an immunologic CTL response (1:24-27; 2:48-52; 3:49-4:40). Martins discloses antigens that provoke cell-mediated immunity through T-cell response and maintaining this immune response over time. Martins explicitly states that his antigens provoke cell-mediated immune responses (3:54-57), indeed, an immune response is central to the Martins' invention. Martins discusses the "immune response, its intensity, and the extent thereof" are aspects of his invention (8:4-5). Martins also discloses his method as protection against an impending disease (5:60 - 6:17). Clearly this involves inducing an immunologic CTL response since the animal has not even encountered the disease at treatment time.

Applicant points out that "cell-mediated immunity" is a broad term and can include monocytes, NK cells, as well as cytotoxic T lymphocytes and that the induction of CTL responses was poorly understood at the filing date of Martins invention. Martins recognizes these various cells responses (4:49-60) and the applicable understanding of CTL response induction is at Applicant's filing date. Martins discloses T-cell response with respect to cell-mediated immune responses and one of ordinary skill in the art at the time of Applicant's invention would read this disclosure as a CTL response.

Applicant has submitted an affidavit stating that there are various scenarios under Martins that likely would not inherently result in induction of a CTL response. Applicant's submitted declaration only states peptide antigens that fall within one of the various types of antigens used

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by Martins would not induce a CTL response as a necessary result. The affidavit is silent concerning all of the other types of antigens disclosed by Martins. The affidavit does not state that all of the antigens disclosed by Martins can not inherently induce a CTL response, but rather selectively chooses one type (peptide antigens) and further narrows this type as a hexamer peptide and nonamer peptide. The affidavit's silence concerning inherent CTL induction with regards to all the antigens disclosed by Martins appears to reinforce the examiner's position that antigens disclosed by Martins induce a CTL response.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be

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reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh  
14 June 2002

  
**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**